REMARKS

In the Office Action, claims 1-10 and 23-31 are rejected. By the present amendment, claims 1-5, 8-10, 23, 24, 27 and 30 are amended.

Objection to the Specification

The Abstract of the disclosure was objected to because of the inclusion of legal phraseology such as the term "comprising". The Abstract is amended herein, wherein "comprising" is replaced with --is provided having at least--, and "means" is replaced with --component--, in compliance with MPEP §608.01(b). Applicants respectfully request that the objection be withdrawn.

Rejections Pursuant to 35 U.S.C. §112, Second Paragraph

Claims 1-10 and 23-31 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In support of the instant rejection, it was initially asserted that claim 1 is indefinite since it is not clear that the same blood sample applied to the application site of the substrate body flows both to the dilution channel and the sample channel so that the "blood sample aliquot to be diluted" recited on line 6 of claim 1 is the same as the blood sample in the dilution channel whose corpuscular blood components are separated, and that claim 1 lacks structural cooperation between the application site of the substrate body and both the dilution channel and the sample channel. In addition, it is asserted that claim 1 is indefinite since it is not clear whether the "blood sample aliquot to be diluted" is a whole blood sample or just some portion of a blood sample (i.e., a particular cell portion such as red blood cells).

Claim 1 is amended herein and now recites "an analytical test element comprising an application site, a microfluidic channel structure in fluid communication with said application site, and at least one analytical site in fluid communication with said microfluidic channel structure." Claim 1 as amended herein further recites the channel structure (which is in fluid communication with the application site) comprises a

dilution channel which comprises separation means for retaining corpuscular blood components of a blood sample applied to the application site and a sample channel, and thereby provides the structural cooperation called for in the Office Action. Claim 1 as amended herein further recites the sample channel is configured to convey an aliquot of a blood sample applied to the application site to be diluted, and which sample channel joins the dilution channel at a mixing site. The dilution channel and the sample channel each contain a portion of the blood sample applied to the application zone, as the dilution channel and the sample channel are defined by the channel structure, which channel structure is in fluid communication with the application site.

Also in the Office Action, with respect to claim 2, is was asserted that the phrase "the sample flow" lacks antecedent basis, and that this claim is indefinite since it is not clear where the junction is located in the apparatus. Claim 2 is amended herein and recites an "analytical test element of claim 1 further comprising a junction in the channel structure downstream of said application site, configured such that a blood sample applied to the application site will flow into both the sample channel and the dilution channel in parallel."

With respect to claim 3, it was asserted in the Office Action that the phrase "the subflows of the blood sample" lacks antecedent basis since claim 1 does not positively recite a blood sample flowing from the application site into two different subflows, one leading to the dilution channel and the other leading to the sample channel. Claim 3 depends from claim 1, which as noted above is amended herein to define an analytical test element comprising an application site, a microfluidic channel structure in fluid communication with said application site, and at least one analytical site in fluid communication with said microfluidic channel structure, *inter alia*. Claim 3 is also amended herein, wherein the phrase "the subflows of" have been deleted.

With respect to claims 4 and 5, the phrase "the flow rate" was said to lack antecedent basis. Claims 4 and 5 are amended herein and recite the analytical test

element of claim 1, wherein the sample flows through the dilution channel at a rate that is more than 10-fold higher than the rate the sample flows through the sample channel, and 100-fold higher than the rate the sample flows through the sample channel, respectively.

With respect to claims 8 and 10, the phrase "the diluted blood sample" was said to lack antecedent basis since claim 1 never positively recites a blood sample that has been diluted. By the present amendment, claims 8 and 10 are amended to delete the term "diluted".

Claim 9 was said to be indefinite since it is not clear where in the apparatus the first and second analytical channels are located in relation to the application site, the dilution channel and the sample channel. Claim 1 is amended herein and recites a structural cooperation among the application site, the dilution channel and the sample channel. Claim 9, which depends from claim 1, is also amended herein and recites "said first and said second analytical channels are positioned downstream of said mixing site."

Also in the Office Action, claim 23 was said to be indefinite since it is not clear where in the analytical test element the liquid components of a blood sample are obtained, where the liquid components are added to "a portion of the blood sample to be analyzed", and where in the analytical test element the dilution of a blood sample takes place. It was also said to be unclear whether the "portion of the blood sample to be analyzed" is the same as the blood sample whose liquid components are obtained somewhere in the device, and whether the "portion of the blood sample to be analyzed" is a whole blood sample or just some portion of a blood sample (i.e., a particular cell portion such as red blood cells). Claim 23 is amended herein and recites a method for carrying out blood analyses comprising providing an analytical test element comprising an application site, a microfluidic channel structure in fluid communication with said application site, and at least one analytical site in fluid communication with said

microfluidic channel structure, applying a blood sample to be analyzed to said application site, moving said blood sample via said microfluidic channel structure from said application site to said at least one analytical site, obtaining liquid components from the blood sample, and adding said liquid components to a portion of the blood sample to be analysed in order to dilute it.

With respect to claim 24, the phrase "the starting material" was said to lack antecedent basis. By the present amendment, this phrase has been deleted from claim 24. Also, the phrase "the subflow that has been depleted of cell components in the dilution channel" was said to lack antecedent basis since it was not previously recited that this occurs in the dilution channel, and that the location of the mixing site is unclear and vague. Claim 24 is amended herein and recites the method of claim 23 further comprising "applying a whole blood sample to the application site, feeding said whole blood sample in parallel subflows into a dilution channel and a sample channel of the channel structure, depleting at least a portion of said whole blood sample of its cell components in the dilution channel, and joining the dilution channel subflow and the sample channel subflow at a mixing site positioned downstream of said dilution channel subflow and said sample channel subflow."

Claims 27 and 30 are amended herein, respectively, such that the phrase "the wall sections" is replaced with --the wall structures--, and the phrase "can be" is replaced with --is--, in accordance with the Examiner's suggestions.

In light of the various amendments made herein as discussed above, applicants submit that the claims are in compliance with the statute, that no new matter has been added, and respectfully request the rejections be withdrawn.

Rejection Pursuant to 35 U.S.C. §102(e)

Also in the Office Action, claims 1, 6-7 and 23 were rejected under 35 U.S.C. §102(e) as being anticipated by Gordon et al. (US 7,087,203). In support of the instant

rejection, it is asserted that since claims 1, 6-7 and 23 do not specify that the same whole blood sample is passed through both the dilution channel and the sample channel from a common application site thus resulting in a whole blood sample being diluted with its own plasma, and does not specify that the blood sample aliquot to be diluted is a whole blood sample, the limitations taught for the bio-disc of Gordon et al. serve to anticipate claims 1, 6-7 and 23 since the bio-disc comprises a microfluidic channel structure having an application site (i.e., 256), an analytical site (i.e., 254), a dilution channel containing a separation means (250) and a sample channel that conveys a blood sample to be diluted (i.e., the channel leading from the application site 256).

Claim 1 is amended herein and recites an analytical test element comprising an application site, a microfluidic channel structure in fluid communication with said application site, and at least one analytical site in fluid communication with said microfluidic channel structure, wherein the channel structure comprises a dilution channel which comprises separation means for retaining corpuscular blood components of a blood sample applied to the application site and a sample channel which conveys an aliquot of the blood sample applied to the application site to be diluted, and which sample channel joins the dilution channel at a mixing site.

Both the dilution channel and the sample channel can be said to be in fluid communication with the application site. As such, the test element can be configured so that different portions of the same blood sample applied to the application site is passed through both the dilution channel and the sample channel, thus resulting is a blood sample being diluted with its own plasma. As noted at para. [0008] of the specification, this enables whole blood that has been applied by the user to be diluted with its own liquid components without having to store additional liquids.

Claim 23 is also amended herein and recites a method for carrying out blood analyses comprising providing an analytical test element comprising an application site,

a microfluidic channel structure in fluid communication with said application site, and at least one analytical site in fluid communication with said microfluidic channel structure, applying a blood sample to be analyzed to said application site, moving said blood sample via said microfluidic channel structure from said application site to said at least one analytical site, obtaining liquid components from the blood sample, and adding said liquid components to a portion of the blood sample to be analysed in order to dilute it.

In contrast, Gordon et al. describe a system for blood typing or the detection of antibodies directed against a particular blood type wherein whole blood or a diluted sample thereof is loaded directly onto a bio-disc into a microfluidic circuit via one application site, and cells of a known blood group phenotype are added through a separate entry port 256. The cellular blood components and the blood sample to be analysed, in this case to be typed, are not from the same blood sample. Claims 6 and 7 depend from independent claim 1 and therefore contain all of the elements of that claim. Consequently, in light of the amendments made herein, Gordon et al. cannot be relied upon in support of the instant rejection as it does not teach or suggest all of the elements of the independent claim. Applicants therefore respectfully request that the rejection be withdrawn.

Rejection Pursuant to 35 U.S.C. §103(a)

Also in the Office Action, claims 4-5 and 25-31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gordon et al. in view of Macho et al. (WO 01/24931). It is asserted in support of the instant rejection that although Gordon et al. fail to teach of the flow rates through the dilution channel and sample channel relative to one another, fail to teach that capillary action with various wall structures and valve elements is used to transport the blood sample through the microfluidic channel structure of the bio-disc, and fail to teach that the microfilter separation means in the dilution channel is a glass fiber fleece or microporous filter matrix, Macho et al. teach of a capillary device for separating undesired components such as blood cells from a liquid sample such as whole blood, and based on the combination of Gordon et al. and Macho

et al., it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use capillary action to transport the blood sample through the microfluidic channel structure of the bio-disc taught by Gordon et al. since Macho et al. disclose that the use of capillary action with porous matrix materials, wall structures and hydrophilized valve elements serve to effectively transport a blood sample through an analytical test element in order to separate blood cells from a whole blood sample. Thus, it is asserted that claims 25-30 would have been obvious because the use of capillary action in an analytical test device to separate blood cells from a whole blood sample was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teachings of Macho et al. Also in support of the instant rejection, it is asserted that it also would have been obvious to one of ordinary skill in the art to use a glass fiber fleece as the microfilter separation means in the bio-disc taught by Gordon et al. since Macho et al. disclose the use of this material as an effective and efficient filter means for separating blood cells from a whole blood sample in order to obtain plasma, which is the purpose of the bio-disc taught by Gordon et al., and that it would have been obvious to one of ordinary skill in the art to adjust the flow rates of the blood sample through the dilution channel and sample channel in the bio-disc taught by Gordon et al. to the rates recited in instant claims 4 and 5 since flow rate is a result effective parameter that can be varied experimentally depending upon the intended use and a desired outcome of a device.

As noted herein, Gordon et al. do not teach an analytical test element comprising an application site, a microfluidic channel structure in fluid communication with said application site, and at least one analytical site in fluid communication with said microfluidic channel structure, wherein the channel structure comprises a dilution channel which comprises separation means for retaining corpuscular blood components of a blood sample applied to the application site and a sample channel which conveys an aliquot of the blood sample applied to the application site to be diluted, and which sample channel joins the dilution channel at a mixing site. Claims 4-5 and 25-31 contain all of the limitations of claim 1 from which they depend and, therefore, Macho et

al. cannot be said to fulfill the deficiencies of Gordon et al. In view of the amendments herein, applicants submit that a *prima facie* case of obviousness has not been established and respectfully request that the rejections be withdrawn.

Indication of Allowable Subject Matter

Also in the Office Action, claims 2-3, 8-10 and 24 were said to be allowable if rewritten to overcome the rejections under §112, second paragraph, and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests an analytical test element for analyzing a whole blood sample that comprises a single application site for a whole blood sample, a junction located proximate to the application site for dividing the blood sample into two parallel subflows, wherein one subflow flows to a dilution channel containing a separation means for retaining corpuscular blood components and another subflow flows to a sample channel that conveys the whole blood sample, and a mixing site located downstream of the dilution and sample channels where plasma separated out in the dilution channel combines with the whole blood sample from the sample channel to dilute the whole blood sample with its own plasma at the mixing site.

Applicants thank the Examiner for this indication of allowable subject matter and reserve the right to later amend or add new claims in line with such allowable scope.

Applicants further note the remaining prior art made of record in the Office Action (i.e., Bhullar et al. (U.S. 6,406,672 and 6,319,719), Hoshino et al., Neumann et al., and Shartle et al.). As that additional art is not applied by the Examiner against the claims of this application, applicants are not providing any comments concerning the same at this time.

CONCLUSION

Applicants respectfully submit that the present application is in condition for allowance. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this amendment. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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